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APPROPRIATE USE CRITERIA

2013 Appropriate Utilization of Cardiovascular Imaging

A Methodology for the Development of Joint Criteria for the Appropriate Utilization of Cardiovascular Imaging by the American College of Cardiology Foundation and American College of Radiology

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Abstract

The American College of Radiology (ACR) and the American College of Cardiology Foundation (ACCF) have jointly developed a method to define appropriate utilization of cardiovascular imaging. The primary role of this method is to create a series of documents to define the utility of cardiovascular imaging procedures in relation to specific clinical questions, with the aim of defining what, if any, imaging tests are indicated to help to determine diagnosis, treatment, or outcome. The methodology accomplishes this aim through the application of systematic evidence reviews integrated with expert opinion by means of a rigorous Delphi process. By obtaining broad input during the development process from radiologists, cardiologists, primary care physicians, and other stakeholders, these documents are intended to provide practical evidence-based guidance to ordering providers, imaging laboratories, interpreting physicians, patients, and policymakers as to optimal cardiovascular imaging utilization. This document details the history, rationale, and methodology for developing these joint documents for appropriate utilization of cardiovascular imaging.

Introduction

Cardiovascular imaging procedures provide essential information for the detection, diagnosis, and management of disease, and serve a vital role in risk assessment and clinical decision making. The relevant procedures include echocardiography, radionuclide imaging, cardiac magnetic resonance, cardiac computed tomography, and invasive coronary angiography. The optimal use of these procedures for specific clinical scenarios is unclear and provides the nidus for the development of appropriate use recommendations. Over the last decade, there has been a tremendous growth in the use of imaging, disproportionate to the growth of other components of healthcare spending. This has led to scrutiny of all medical imaging and, in particular, imaging related to cardiovascular care. The reasons for the growth of imaging are many: however, perceived improvement in patient care by both providers and patients is a driving factor. At the same time, appropriate utilization has been questioned due to the geographic variability in the use of cardiovascular imaging procedures, unexplained by differences in patient demographics or risk factors (1,2). In an effort to contain the growth and associated costs of cardiac imaging, payers have adopted various approaches, including prior authorization, in an effort to limit testing. A crucial concern is that these controls may limit patient access to the appropriate imaging procedures and/or direct patients to higher cost through delay in diagnosis or layered testing diagnostic approaches. Additionally, pre-authorization frequently relies on proprietary algorithms, is inconsistent with published literature

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and/or guidelines, and methodologies vary greatly among payers and regions of the country.

Clinical guidelines and performance measures have been successfully developed for years, and their positive impact on patient outcomes has been well demonstrated. However, the evaluation of the impact of diagnostic tests on patient outcomes presents unique challenges (3). Methods and funding to evaluate diagnostic testing have lagged behind those related to treatments (4). In a similar manner, using an appropriate testing strategy (i.e., clinical guidelines) is increasingly recognized as an important determinant of healthcare quality (5).

Historical Perspective

The American College of Cardiology Foundation (ACCF) and American College of Radiology (ACR) have both produced appropriate use guidance documents in an effort to delineate recommended utilization of cardiovascular imaging. The ACR Task Force on Appropriateness Criteria was created in 1993 to develop nationally accepted, evidence-based, methodologically sound clinical guidelines, called "appropriateness criteria," to assist referring physicians in making appropriate imaging decisions. These criteria are developed beginning with a systematic critical review of published literature on the topic. Ratings are performed based on the evidence and supplemented by expert opinion as needed, and then finalized using a modified Delphi process. These ACR Appropriateness Criteria (AC) are developed using a carefully defined, reproducible methodology and cover the spectrum of diagnostic, interventional, and therapeutic procedures. Each AC addresses a specific clinical scenario, generally with variants as necessary, to address clinical reality. As of the June 2012 release, there are 180 ACR Appropriateness Criteria topics addressing over 850 disease process variants (6). Each AC document is updated every 2 years.

The ACCF has published clinical guidelines and performance measures for more than 25 years, and in 2004, initiated the development of appropriate use criteria in conjunction with the ACR, the American Heart Association, and cardiovascular subspecialty societies, in order to provide physician-specific guidance when considering utilization of cardiovascular imaging and other technology. To date, these efforts have been modality specific for imaging but have considered multiple technologies for revascularization. The ACCF method also draws upon the available evidence base and utilizes a modified Delphi process to support a systematic evaluation of expert opinion (7). As of 2010, 6 appropriate use documents, each encompassing 50 to 200 clinical scenarios, have been published (8–13).

Goals

The primary goal of the current initiative is to harmonize the separate efforts of the ACR and ACCF as related to cardiovascular imaging and to provide consistent and authoritative guidance to the healthcare community. The joint effort by ACCF and ACR maintains a rigorous, but transparent, methodology that includes the comparative and multimodality imaging features of the ACR approach, as well as the more specific set of clinical presentations contained within the ACC method. This joint approach uses the best elements of both societies' approaches by selecting clinical scenarios of high impact to patient care and determining the cardiac imaging strategy that best provides optimal and value-added patient care.

Definition of Appropriateness

Appropriateness methodology was initially described in the 1980s by RAND Corporation/University of California Los Angeles as part of the Health Services Utilization Study (14) (see Appendix A for additional details). The definition for appropriate utilization is derived from the goals of the AQA alliance, a multistakeholder collaborative of physicians and other healthcare providers, consumers, purchasers, and health plans focused on improved patient safety, healthcare quality, and value (15,16). The new method adheres to the following definition: "The concept of appropriateness, as applied to health care, balances risk and benefit of a treatment, test, or procedure in the context of available resources for an individual patient with specific characteristics. Appropriateness criteria should provide guidance to supplement the clinician's judgment as to whether a patient is a reasonable candidate for the given treatment, test, or procedure." (16, para. 2). From conception to publication, the joint ACR/ACCF process adheres to the aforementioned goals, with each document on appropriate utilizations of cardiovascular imaging based, to as great an extent as possible, on available high-quality clinical data, supplemented as necessary by expertise and insights from other sources. The process is represented in Figure 1.

Organizational Structure

The success of the process relies on the oversight committee and staff to assemble physicians who are experts in the clinical conditions and/or in imaging modalities, to form the writing panels, review panels, and rating panels in a way that will produce balanced recommendations based on the peer-reviewed evidence that do not favor any specific approach or discipline (Table 1).

1. The **Oversight Committee** provides methodological oversight, defines the scope of documents, and supports continuity across panels and among documents.

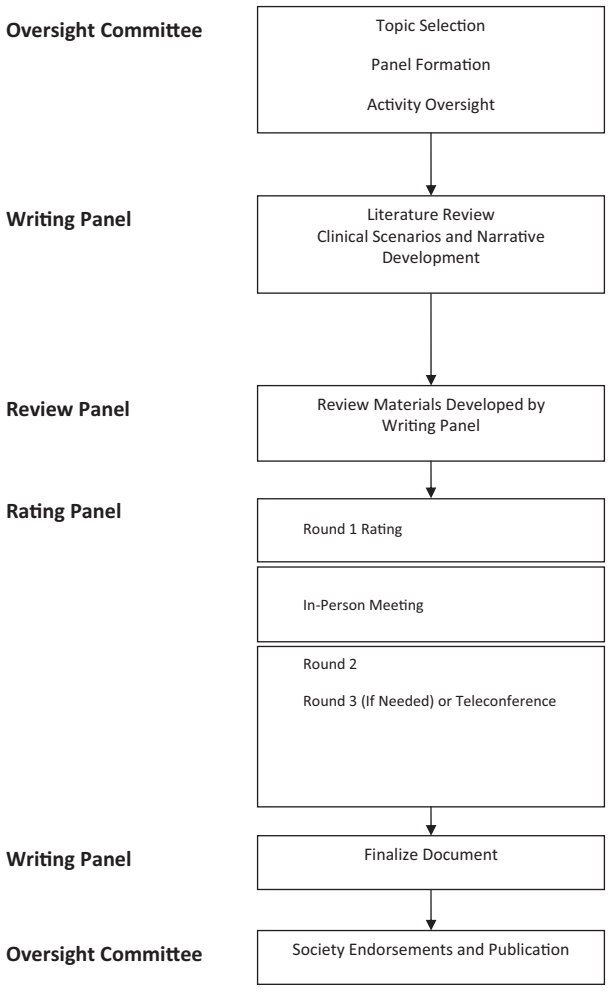

Figure 1. Organizational Structure for ACR/ACCF Appropriateness Criteria Process

The committee is also responsible for helping to select individuals to serve on the writing, review, and rating panels, and for providing review and approval at each stage of the process.

2. The **Writing Panel** identifies clinical indications and scenarios that are relevant for clinical decision making and the use of cardiovascular imaging. The writing panel systematically evaluates and categorizes literature with respect to each indication/scenario. The panel constructs a narrative summary of the evidence and accompanying evidence tables for each indication/scenario relative to the application of cardiovascular imaging modalities.
3. The **Review Panel** provides critical review and recommendations on refining the indications/scenarios, narratives, literature cited, and evidence tables before the rating process.
4. The **Rating Panel** reviews the prepared narratives and evidence tables, and rates the appropriateness of the use of imaging for the specific clinical indications. The panel performs an initial round of rating followed by an in-person meeting to discuss and further refine the indications and evidence, if needed. A second, and possibly third, round of rating on appropriateness will occur to determine the final appropriateness ratings.

Elements of Appropriateness Criteria Development

Indications/Scenarios, Evidence Review, and Narrative Development

The general indications and their specific scenarios are selected to reflect specific clinical scenarios for which various imaging procedures may be considered and that may have a large impact on patient care. Scenarios will address concepts such as clinical utility, requisite expertise and indications, and timing for repeat testing for surveillance or altered clinical status. Separate clinical indications will be created to allow for differences in patient risk or disease likelihood categories and prior test results (e.g., laboratory tests or electrocardiograms). To help support eventual implementation, clinical indications should be able to be measured objectively and contain discrete data elements that are feasible to collect at the time of ordering.

The narrative and evidence tables for each indication will summarize the available evidence. They will describe the strengths and limitations of the evidence favoring organized research over expert opinion. Stronger study design meth-

Table 1. Oversight Committee and Panel Membership Criteria

Name	Number of Members	Composition
Oversight committee	12–16	Equal representation from ACCF and ACR.
Writing panel	6–10	Equal representation of imaging experts from cardiology and radiology. Member(s) of the oversight committee are included on the writing panel to provide methodology guidance and continuity. Additional experts in clinical medicine, health economics, comparative effectiveness, or other content areas are recruited as needed.
Review panel	20–40	Content experts and stakeholders selected from societal and stakeholder nominations to broadly represent medical specialty organizations and other groups relevant to the topic.
Rating panel	15–19	Cardiology, radiology, physicians who order tests, and other expertise; must be an odd number; imaging physicians are to comprise no more than 66% of the panel. Cardiology and radiology may not have equal representation, to ensure adequate clinical expertise.
Overall total	53–85	Cardiology, radiology, physicians who order tests, and other expertise.

ACCF = American College of Cardiology Foundation; ACR = American College of Radiology.

Table 2. Appropriateness Categories and Scores

Score	Category	Description
1, 2, or 3	Rarely appropriate	Rarely an appropriate option for management of patients in this population due to the lack of a clear benefit/risk advantage; rarely an effective option for individual care plans; exceptions should have documentation of the clinical reasons for proceeding with this care option (i.e., procedure is not generally acceptable and is not generally reasonable for the indication).
4, 5, or 6	May be appropriate	At times an appropriate option for management of patients in this population due to variable evidence or agreement regarding the benefit/risk ratio, potential benefit based on practice experience in the absence of evidence, and/or variability in the population; effectiveness for individual care must be determined by a patient's physician in consultation with the patient based on additional clinical variables and judgment along with patient preferences (i.e., procedure may be acceptable and may be reasonable for the indication).
7, 8, or 9	Appropriate	An appropriate option for management of patients in this population due to benefits generally outweighing risks; effective option for individual care plans although not always necessary, depending on physician judgment and patient-specific preferences (i.e., procedure is generally acceptable and is generally reasonable for the indication).

The rating scale is composed of discreet integers from 1 to 9. The available knowledge base of evidence for rating each scenario varies from extensive to limited or none. Each member of a rating panel considers the available evidence, which may be limited, unclear, or even conflicting, and using their expertise and experience, determines their individual rating for each modality in the scenario. The modified Delphi technique is robust as a methodology for handling differences in interpretation of the evidence-based and varied expertise among the rating panel members. Imaging procedures for a clinical scenario with a rating in the maybe appropriate category may indicate the need for additional evidence to move the rating into either the rarely appropriate or appropriate rating ranges.

odology will receive greater weight, increasing from observational series, multicenter series, and randomized or controlled clinical trial data. When studies of the imaging modality in a specific clinical indication are not present, relevant publications for related topics or using similar tests may be included but with the limitations clearly indicated.

A narrative will then be constructed for each broad class of indications, serving as an objective summary of key literature. The review of the evidence should include:

1. Clinical rationale—reason for examining the patient
2. Imaging rationale—reason for the use of imaging
3. Literature review summary statement—description of the clinical performance of each test for the specific indications. A review of the evidence supporting use of each imaging modality to understand specific clinical parameters and the technical capabilities required to support these uses may be helpful in constructing the summary statement. This detailed review of imaging parameters may be provided as an appendix and examines the role of each parameter in defining incidence and providing information for diagnosis, prognosis, and guiding treatment
4. Evidence table—lists key articles from the summary statement, categorizes study design, and rates the strength of scientific evidence

To provide a foundation for the writing panel, the oversight committee develops material providing an overview of cardiovascular imaging procedures and safety considerations (see Appendix B). These foundational materials include a review of the technical capabilities of each test to examine various clinical parameters, as well as issues related to patient safety (e.g., radiation exposure, contrast agents, other pharmaceuticals used during the procedure). These materials will be referenced, updated, and expanded by the successive writing panels as required. All documents also are to assume that the imaging procedures are performed using accepted image acquisition protocols, in accredited facilities, using accepted standards of reporting by personnel credentialed to perform and interpret the test.

Review Process

The indications/scenarios, narrative, literature review, and evidence table are then sent to the review panel, whose purpose is to ensure the indications are both clear and reflect clinical practice; and that the literature review provides sufficient material to facilitate the rating process. The review panel is expected to suggest indication consolidation and/or expansion, provide additional key references, and make suggestions to improve overall clarity and clinical applicability.

Rating Process

The rating panel use a 1 to 9 scale to rate the appropriateness of an imaging procedure for the specific indication/scenario (Table 2). There are 3 categories that define this scale, where 1, 2, or 3 represents the "rarely appropriate" category; 4, 5, or 6 represents the "maybe appropriate" category; and 7, 8, or 9 represents the "appropriate" category. The maybe appropriate category is further specified into 3 subcategories. The maybe appropriate category indicates that the rating panel agreed that: 1) there was insufficient evidence on whether the imaging procedure was appropriate or not; or 2) the available evidence was equivocal or conflicting; or 3) additional factors beyond those described must be considered. A maybe appropriate rating is more likely with procedures using new technology or protocols for which the evidence is limited and additional research is required. All raters recognize that a rating in the maybe appropriate category does not invalidate the use of specific imaging on a case-by-case basis when the best interests of an individual patient are being considered by the caring physician. The ACCF and the ACR recommend that a maybe appropriate category not be used as justification for the nonpayment of imaging services.

Rating panel members initially vote independently on the appropriateness of each imaging procedure for all the clinical indications. The results are then tabulated and returned to the rating panel members in the form of their individual scores along with the de-identified scores from the other members. A mandatory in-person meeting of the rating panel is then held to review and propose indication revisions to the writing panel. The in-person meeting includes nonrating representatives of the writing panel and oversight committee, who provide guidance relative to procedural and operational issues and ensure continuity throughout the process. The oversight committee representative also serves as an unbiased moderator to the rating panel and facilitates optimal group dynamics during the process. The oversight committee moderator must be free of significant relationships with industry and be unbiased relative to the topics under consideration. The revised narrative and indications then undergo a second round of independent rating. If a significant dispersion of scores is still present, a conference call and/or third round of rating will occur. Sufficient agreement is achieved for a topic if ≥60% of the rating scores fall within 1 of the 3 categories (e.g., appropriate, maybe appropriate, or rarely appropriate).

Endorsement and Publication

Once the rating process has concluded, additional modifications of indications, scores, and narrative/evidence tables are not possible. This critically preserves the integrity of the Delphi process, which cannot be influenced post hoc. The final document, including summary tables and/or figures, will be assembled by the writing panel and submitted to the oversight committee for approval, and then submitted to the boards of the ACCF and ACR for approval before publication. Other societies and organizations may be invited to endorse the manuscript.

Application of Appropriate Utilization Documents

Appropriate utilization of imaging is the shared responsibility of clinicians who use imaging to guide clinical decision making in patient care on one hand, and of physicians who perform imaging procedures and understand the strengths and limitations of imaging technology on the other. Accordingly, these documents are designed to improve clinical cardiovascular care through judicious use of cardiovascular imaging. The intended audience for these documents is diverse, including clinicians, patients, payers, and policymakers. Indications do not always require specific imaging, and procedures rated rarely appropriate may, under certain circumstances, be fully justified. Possible applications of the appropriate use documents include incorporation into decision support systems (including computerized physician order entry), integration into laboratory accreditation standards, and as a means to provide critical feedback and education to healthcare providers as to appropriate imaging decision making.

Conclusions

The ACCF and the ACR have collaborated in creating a rigorous combined method for the development of criteria for the appropriate utilization of cardiovascular imaging based on real-world clinical scenarios. The resulting criteria can be combined with the prior efforts of both organizations to ensure high value use of cardiovascular imaging.

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Key Words: ACCF Appropriate Use Criteria ■ appropriateness criteria ■ appropriate utilization ■ heart failure ■ imaging ■ methods ■ multimodality.

APPENDIX A. DEFINITION OF APPROPRIATENESS AND UNDERLYING METHODOLOGY

The methods presented are based on the Appropriateness Method originally developed in the 1980s as part of the RAND Corporation/University of California Los Angeles (UCLA) Health Services Utilization Study (14) and the extensive combined experience of the ACR and ACCF in applying these methods. In their report on the RAND methodology, Brook et al. defined care as appropriate when "the expected health benefit (i.e., increased life expectancy, relief of pain, reduction in anxiety, improved functional capacity) exceeded the expected negative consequences (i.e., mortality, morbidity, anxiety…pain…time lost from work) by a sufficiently wide margin that the procedure is worth doing" (56, p. 3). Instructions specified that this definition should be applied exclusive of cost when judging the appropriateness of indications. The AQA Alliance (formerly "Ambulatory Care Quality Alliance," renamed to reflect the expansion of the mission beyond ambulatory care) was formed in 2004. As participants in AQA alliance activities, the ACR and ACCF base their views of appropriateness on the AQA alliance's definition of appropriateness:

> The concept of appropriateness, as applied to health care, balances risk and benefit of a treatment, test, or procedure in the context of available resources for an individual patient with specific characteristics. Appropriateness criteria should provide guidance to supplement the clinician's judgment as to whether a patient is a reasonable candidate for the given treatment, test or procedure (16, para. 2).

The ACCF has modified this concept to include an analysis of explicit cost in their definition of an appropriate imaging procedure. The ACCF definition is:

> An appropriate imaging study is one in which the expected incremental information, combined with clinical judgment, exceeds the expected negative consequences* by a sufficiently wide margin for a specific indication that the procedure is generally considered acceptable care and a reasonable approach for the indication.
> **Negative consequences include the risks of the procedure (i.e., radiation or contrast exposure) and the downstream impact of poor test performance such as delay in diagnosis (false negatives) or inappropriate diagnosis (false positives)* (7, p. 1607).

The Appropriateness Method relies on the tenets of evidence-based medicine to integrate scientific evidence and expert opinion (15,16). The Appropriateness Method is different from "consensus methods" in that the objective is not to develop a consensus among experts but to see whether experts agree or disagree, and to what extent, given the available evidence. The Appropriateness Method is an extension of the Delphi method, also developed by the RAND Corporation, for predicting future events. In the modified Delphi method, material is circulated among a group of experts who are asked to rate various scenarios. These answers are tabulated and presented to the group for discussion before each additional round for a maximum of 3 rounds.

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APPENDIX B. IMAGING PROCEDURES AND SAFETY INFORMATION

Modality	Variations	Contrast/Isotope	Contrast Agent	Potential Contrast-Related Issues	Cannulation Needs	Potential Cannulation-Related Issues	Other Potential Issues	Radiation Exposure Ranges (mSv)
Echocardiography	Transthoracic	Infrequent	Microbubble	Reaction (5,18–20)	Venous for contrast	Peripheral vein injury (21)	NA	NA
	Exercise stress contraction transthoracic	(+)/(−)	Microbubble	Reaction (5,18–20)	Venous for medications/ contrast	Peripheral vein injury (21)	Stress-related (22)	NA
	Pharmacological stress contraction transthoracic	(+)/(−)	Microbubble	Reaction (5,18–20)	Venous for medications/ contrast	Peripheral vein injury (21)	Stress-related (22)	NA
	Transesophageal	(−)	NA	NA	Esophageal for probe	Esophageal perforation (23,24)	Sedation (25)	NA
					Venous for medications	Peripheral vein injury (21)		
CMR	Anatomic/functional	(+)/(−)	Gadolinium	Reaction (26–28) NSF (29–31)	Venous for contrast		Sedation (25) Tissue burn/ metallic attraction/ electronic dysfunction (32–34)	NA
	Pharmacological stress/ rest perfusion	(+)	Gadolinium	Reaction (26–28) NSF (29–31)	Venous for medications/ contrast		Medication-related Tissue burn/ metallic attraction/ electronic dysfunction (32–34)	NA
	Pharmacological stress contraction	(−)	NA	NA	Venous for medications	Peripheral vein injury (21)	Stress-related (35) Medication-related Tissue burn/ metallic attraction/ electronic dysfunction (32–34)	NA
CCT	Enhanced	(+)	Iodine	Reaction (21,26,36,37) CIN (21,38–40)	Venous for medications/ contrast	Peripheral vein injury (21)	Medication-related	1–28 mSv (41–50)
SPECT	Rest perfusion	NA	NA	NA	Venous for radionuclide	Peripheral vein injury (21)	NA	4–20 mSv (42,43,49–51)
	Pharmacological stress/ rest perfusion	Technetium, thallium, etc.	NA	NA	Venous for medications/ radionuclide		Medication-related	9–41 mSv (42,43,49–51)
PET	Rest perfusion	Rubidium, etc.	NA	NA	Venous for radionuclide	Peripheral vein injury (21)	NA	5–8 mSv (42,43,49–51)
	Pharmacological stress/ rest perfusion	NA	NA	NA	Venous for medications/ radionuclide	Peripheral vein injury (21)	Medication-related	10–16 mSv (42,43,49–51)
	Rest metabolism	NA	NA	NA	Venous for radionuclide	Peripheral vein injury (21)	NA	7–14 mSv (42,43,49–51)
Invasive coronary angiography	Left heart	(+)	Iodine	Reaction (21,26,36,37) CIN (21,38–42)	Arterial for contrast Venous for medications	Coronary/aortic/ peripheral artery injury (52–54) Peripheral vein injury (21)	Sedation (25) Embolization Ventricular arrhythmia (52–54)	2–23 mSv (43,55)
	Right heart	(+)	Iodine	Reaction (21,26,36,37) CIN (21,38–40)	Venous for medications/ contrast	Coronary/caval/ peripheral vein injury (21,52–54)		

CCT = cardiac computed tomography; CIN = contrast-induced nephropathy; CMR = cardiac magnetic resonance; NA = not applicable; NSF = nephrogenic systemic fibrosis; PET = positron emission tomography; SPECT = single-photon emission computed tomography.